

PATENT
Attorney Docket No. 056159-5047-US
U.S. Appl. No. 09/582,296

REMARKS

Upon entry of the foregoing amendment, claims 1-9 are pending in this application. Claims 7-9 have been withdrawn from examination as being directed to a non-elected invention. Claims 1-6 are currently under examination, having been orally elected by Paul Kokulis in the May 21, 2002 telephone conversation with the Examiner.

Claim 1 is the sole independent claim. Support for the amendments to claim 1 is found, *inter alia*, on pages 12-16 (Examples 2-4); page 5, lines 6-10; and, elsewhere throughout the specification. Amendments to claims 2-6 were made for grammatical purposes and to clarify the claimed invention. Support for amendments to claim 2-6 is found, *inter alia*, in original claims 2-6; and, elsewhere throughout the specification.

No new matter is believed to have been added. In view of the amendments and following remarks, reconsideration of the rejections and withdrawal thereof is respectfully requested.

Restriction Requirement

Applicants confirm the election of Group I (claims 1-6), with traverse, in the telephone conversation of May 21, 2002 between the Examiner and Paul Kokulis. Applicants traverse the restriction requirement since it is believed that a search of the protein would encompass, and overlap with, a search of the inventions of Groups II (nucleic acid) and III (food product). Since a search of Group I would encompass and overlap with a search of Groups II and III, an examination of all the claims would not constitute an "undue burden" on the Examiner. It is respectfully requested that the inventions of Groups I-III be examined as a whole. Reconsideration and withdrawal of the restriction requirement is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

At page 4 of the Office Action, the Office rejects claims 1-6 under 35 U.S.C. § 112, first paragraph, because the specification while being enabling for anti-freeze protein, does not reasonably provide enablement for modified versions and isoforms of the protein. The rejections are respectfully traversed. Claims 1-6 have been newly amended.

The Office asserts the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the modified versions or isoforms of the protein commensurate in scope with these claims. The Office, reciting the factors of *In re Wands*, concludes undue experimentation by those skilled in the art would be required because the specification fails to provide adequate disclosures, examples, teachings and guidance.

However, the phrase “and isoforms” has been deleted from claims 1 and 2. Contrary to the position of the Office, the specification provides support for the phrase “modified versions” on page 5, second paragraph. The phrase “modified versions” is a term which is conventional in protein chemistry and is used here in its conventional sense to indicate a covalently attached group which does not affect the ice recrystallization inhibition properties. The specification recites glycosylation as an example (“such as glycosylated versions”) of a modification, not as the only modification, and one of skill in the art would be able to obtain versions of the protein having covalently attached groups which do not affect the ice recrystallization inhibition properties using the methods disclosed in the specification (See, for example, Example I, pages 9-11, disclosing two methods of testing ice recrystallization inhibition properties).

In view of the above remarks and the amendments to the claims, reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

At page 7 of the Office Action, the Office rejects claims 1-6 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejections are respectfully traversed. Claims 1-6 have been newly amended.

The Office argues claims 1 and 2 are indefinite and require some functional limitations. Claims 1 and 2, as newly amended herein, are believed to overcome the rejection. In claim 1, as newly amended, the phrase “at least 80% overlap” is now believed to clearly indicate the modified version has “at least 80% overlap” with the claimed amino acid sequence.

The Office argues claim 1 refers to 80% identify to SEQ ID NO: 1 but fails to define which approximately 3.6 amino acid residues can be changed. The Office also argues claim 2 fails to define which four amino acid residues can be nonidentical.

Contrary to the position of the Office, Applicants are not required to “define” which residues can be changed or be nonidentical. The claim clearly claims an “at least 80% overlap” and the specification clearly explains the method of calculating the overlap (specification pages 3-5). If this rejection is maintained, the Office is respectfully requested to point out with particularity which statute, rule or “Examination Guideline(s)” requires Applicants to “define” which residues can be changed or be nonidentical. In addition, both claims 1 and 2 claim “at least 80% overlap” thereby mooting the question posed by the Office (page 8, line 2-3).

The Office argues claim 5 is indefinite as to 100% overlap as SEQ ID NO: 1 and 2 are not identical. However, claim 5 is not indefinite. Claim 5 claims an antifreeze protein having 100% overlap with the sequence of claim 1 OR claim 2. Claim 5 does not required identity of sequence between claims 1 and 2. If this rejection is maintained, the Office is respectfully

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requested to explain in detail why claim 5 is indefinite so that Applicants may address the Office concerns in detail in the next communication.

The Office argues claim 6 is indefinite because there is no antecedent basis *per se* for “the modification” since claims 1 and 2 recite “modified versions.” The Office further argues that claim 6 is indefinite as to how or what the modification is that involves glycosylation. However, Claim 6, as newly amended, is believed to overcome the rejection.

It is believed the rejections have been overcome in view of the arguments above and amendments to the claims. Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Rejections under 35 U.S.C. § 102(b)

Rejection over Carson *et al.*

At page 8 of the Office Action, the Office rejects claim 1 under 35 U.S.C. § 102(b) as being anticipated by Carson *et al.* [Carson *et al.*, WO 94/14472 (1994); hereafter, “Carson”]. The rejection is respectfully traversed. Claim 1 is newly amended.

The Office asserts that Carson is an applicable reference based on a claim interpretation that modified versions and isoforms are not required to be 80% identical. However, claim 1, as newly amended, is believed to overcome the rejection since it is clear that the modified version shows at least 80% overlap. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection over Alkhatib *et al.*

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At page 8 of the Office Action, the Office rejects claim 2 under 35 U.S.C. § 102(b) as being anticipated by Alkhatib *et al.* [Alkhatib *et al.*, Virology 159: 479-490 (1986); hereafter, “Alkhatib”]. The rejection is respectfully traversed. Claim 2 is newly amended.

The Office asserts Alkhatib shows a sequence from Db 584-599 that is 42% identical to SEQ ID NO: 2 of claim 2. The Office asserts Alkhatib is an applicable reference based on a claim interpretation that modified versions and isoforms are not required to be identical to claim 1.

However, claim 2 depends from claim 1. By convention, a dependent claim includes all the limitations of the claim from which it depends. Therefore, claim 2 includes the text “at least 80% overlap.” As such, Alkhatib fails to teach an amino acid sequence having “at least 80% overlap” with the amino acid sequence of claim 2. Since Alkhatib fails to teach each and every element of the claim, the Alkhatib document fails to anticipate the claim.

In view of the amendments to claim 1, the rejection of dependent claim 2 is believed to be overcome. Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned at his convenience.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including

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fees due under 37 C.F.R. § 1.16 and § 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

This paragraph is intended to be a Constructive Petition for Extension of Time in accordance with 37 C.F.R. § 1.136(a)(3).

Dated: December 2, 2002
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

The claims have been amended as follows:

1 (Twice Amended). A purified anti-freeze [Anti-freeze] protein [which can be derived from Lichen, said protein] having an apparent molecular weight of from 20 to 28 kDa and having an N-terminal amino acid sequence which shows at least 80% overlap with:

A-P-A-W-M-D-A-E-S-F-G-A-I-A-H-G-G-L (SEQ ID NO: 1) and modified versions [and isoforms] of this protein, wherein the modified version of the protein has a covalently attached group which does not affect the ice recrystallization inhibition properties.

2 (Twice Amended). The anti-freeze [Anti-freeze] protein of claim 1 having an N-terminal amino acid sequence as follows: A-P-A-V-V-M-G-D-A-E-S-F-G-A-I-A-H-G-G-L (SEQ ID NO: 2) [and modified versions and isoforms of this protein].

3 (Once Amended). The anti-freeze [Anti-freeze] protein of claim 1 or 2, having a molecular weight of from 22 to 26 kDa.

4 (Once Amended). The anti-freeze [Anti-freeze] protein of claim 1 or 2, showing at least 90% overlap with the [partial] amino acid sequences of claim 1 or claim 2.

5 (Once Amended). The anti-freeze [Anti-freeze] protein of claim 1 or 2, showing 100% overlap with the [partial] amino acid sequences of claim 1 or claim 2.

6 (Once Amended). The anti-freeze [Anti-freeze] protein of claim 1, wherein the [modification involves glycosylation] modified version of the protein is a glycosylated protein.